

## **REMARKS/ARGUMENTS**

This is responsive to the Non-Final Office Action mailed November 9, 2009. In that Office Action, claim 71 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 64, 123, 124, 125, and 127-131 were rejected under 35 U.S.C. §102(e) as being anticipated by LaFontaine et al., U.S. Patent No. 6,443,158 ("LaFontaine"). Claims 66, 67, 71, 74, 126, 132, 139, and 140 were rejected under 35 U.S.C. §102(e) as being anticipated by Nobles et al., U.S. Patent No. 5,944,730 ("Nobles"). Claim 75 was rejected under 35 U.S.C. §103(a) as being unpatentable over Nobles in view of Ho et al., U.S. Patent No. 6,514,265 ("Ho"). Claims 133, 134, 137, and 141 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nobles in view of Marks, U.S. Patent No. 5,108,420 ("Marks"). Claim 136 was rejected under 35 U.S.C. §103(a) as being unpatentable over Nobles in view of LeMole, U.S. Patent No. 5,893,369 ("LeMole"). The Examiner's indication that claims 76-81 have been allowed, and that claims 69, 70, 72, and 73 recite allowable subject matter, is noted with appreciation.

With this Response, claims 64, 66, 71, 123, 127, and 128 have been amended. Claims 64, 66-81, and 123-141 remain pending in the application and are presented for reconsideration and allowance.

### **Miscellany**

The Office Action Summary indicates that claims 68, 135, and 138 have been rejected. However, no rejection of claims 68, 135, or 138 is provided in the Detailed Action. Applicant assumes, therefore, that claims 68, 135, and 138 are only objected to as being dependent upon a rejected base claim. To the extent the Office Action intended to reject any of claims 68, 135, or 138, clarification is respectfully requested.

### **35 U.S.C. §112, Second Paragraph, Rejection**

With this Response, claim 71 has been amended to address the §112, second paragraph, concerns noted in the Office Action. In particular, claim 71 has been amended to more definitively reference "the step of connecting the graft to the vessel at the opening" as otherwise

set forth in claim 66 from which claim 71 depends. Withdrawal of the rejection under §112, second paragraph, is respectfully requested.

### **35 U.S.C. §§102, 103 Rejections**

#### ***LaFontaine Rejections***

LaFontaine relates to a system and method for percutaneous coronary artery bypass through a venous vessel. Initially, and as shown in FIG. 3, proximal and distal ends of a restriction 22 in a coronary artery 16 are located. Occlusion members 30, 32 are then positioned in a vein 20 adjacent the coronary artery 16 as shown in FIG. 4B. *LaFontaine at col. 4, ll. 7-14.* The patient is either placed on full cardiopulmonary bypass, or occlusion members 76, 78 are formed in the coronary artery 16 as shown in FIG. 5B. *LaFontaine at col. 5, ll. 17-26.* An elongate portion or tubular member 58 of a cutting device 56 is inserted into the artery 16 (FIG. 5A); steered outwardly through a wall of the artery 16 and into the vein 20 (FIG. 5B); and then steered outwardly through the wall of the vein 20, through a wall of the artery 16, and back into the artery 16 (FIG. 5D). Subsequently, the tubular member 58 is removed, leaving only a guide wire 66 as shown in FIG. 5E. An introducer 88/90 carrying a previously-mounted graft 86 is then fed over the guide wire 66 and along the cut path through and between the artery 16 and the vein 20, resulting in the arrangement of FIG. 6C. Ends of the graft 86 are then secured to an interior of the artery 16 via stents 94, 96. In formulating the rejections under §102(e) based on LaFontaine, the Office Action references LaFontaine as mentioning the graft 86 optionally being “inserted concurrently” with the cutting device tubular member 58. With this understanding of LaFontaine in mind, it is respectfully submitted that the rejections of independent claims 64, 123, 127, and 128 should be withdrawn for the reasons below.

#### **Independent Claim 64**

Independent claim 64 recites a method for performing an anastomosis while maintaining blood flow within a vessel. As amended, claim 64 further clarifies the inventive method, reciting that blood flow within the vessel across the region at which the cannula extends is maintained. Blood flow is also maintained while the graft is attached to the vessel. Support for this language is found, for example, at page 1, lines 15-17; page 5, lines 9-10; and FIGS. 7-14. In contrast, LaFontaine specifies that either the heart is stopped (and thus blood flow is not maintained), or

the occlusions 30, 32 and/or 76, 78 are deployed to stop blood flow across the artery 16 and the vessel 20 in the corresponding region where the tubular member 58 or 88 passes through and extends within the artery 16 and the vessel 20. *LaFontaine at col. 5, ll. 17-23; FIG. 6C*. Thus, claim 64 is allowable over *LaFontaine*, as are claims 124 and 125 depending thereon.

### **Independent Claim 123**

Independent claim 123 recites a method for performing an anastomosis while maintaining blood flow within a vessel. In contrast, and as described above, *LaFontaine* requires that blood flow not be maintained. *LaFontaine at col. 5, ll. 17-23; FIG. 6C*. Claim 123 has been amended to further clarify that blood flow within the vessel is not occluded. The heart bypass technique or the use of the occluding members 30, 32 and 76, 78 teach away from this feature. Further, claim 123 recites passing the cannula through the vessel wall and into an interior of the vessel, followed by extension through the vessel wall from the interior (e.g., exterior to interior passage, followed by interior to exterior extension); in direct opposition, *LaFontaine* teaches interior to exterior passage, followed by exterior to interior extension. For at least these reasons, it is respectfully submitted that claim 123 is allowable over *LaFontaine*.

### **Independent Claim 127**

Independent claim 127 recites passing a first end of a tubular member from an interior of vessel through a wall of the vessel at a first vessel wall location. As amended, claim 127 further recites that with this passing of the first end of the tubular member, the first end is external the vessel. Further, claim 127 has been amended to recite that a graft is connected to the first end is external the vessel; in this regard, prior to passing of the first end from the interior of the vessel, the graft is not connected to the first end. Support for this language is found, for example, in FIGS. 7-11. In contrast, *LaFontaine* requires that prior to deployment into the artery 16 or the vein 20, the graft 86 is connected to the tubular member 88 (or the cutting device tubular member 58). *LaFontaine at col. 7, ll. 33-39*. Thus, regardless of where the Office Action views the claimed “first vessel wall location” being defined along the artery 16 or the vessel 20, *LaFontaine* does not disclose a method in which the graft 86 is not connected to the tubular member 88 (or 58) prior to passing the first end of the tubular member from the interior of the vessel and through the vessel wall. Further, in FIG. 6C of *LaFontaine*, the graft 86 is secured to the vessel

16 via the stent 94 that is otherwise spaced from the vessel wall location at which the tubular member 88 (or 58) passes through the vessel wall. Thus, the methodology of LaFontaine does not teach “attaching the graft to the first vessel wall location” as otherwise set forth in claim 127. For at least these reasons, independent claim 127, as well as claims 129-131 depending thereon, are allowable over LaFontaine.

#### **Independent Claim 128**

Independent claim 128 recites that a tubular member is initially passed through a vessel wall at a second location to deliver a first end of the tubular member into an interior of the vessel before passing the first end of the tubular member from the interior through the vessel wall at a first vessel wall location. In addition, claim 128 recites that a graft is attached to an exterior of the vessel wall adjacent the first end of the tubular member. In contrast, LaFontaine discloses passing of the tubular member 58 or 88 from an interior to an exterior of the vessel 16, followed by passage from the exterior to the interior. In other words, claim 128 recites exterior to interior passage, followed by interior to exterior passage; LaFontaine discloses interior to exterior passage, followed by exterior to interior passage. Further, FIG. 6C of LaFontaine makes clear that the graft 86 is attached to the interior of the vessel 16 wall, in direct opposition to claim 128. For at least these reasons, it is respectfully submitted that claim 128 is allowable over LaFontaine.

#### ***Rejections Based on Nobles***

Independent claim 66 was rejected as being anticipated by Nobles, and relates to a method for performing an anastomosis on a vessel wall. An opening is formed in a wall of a blood vessel, and a portion of the wall where the opening was formed is removed. In this regard, claim 66 has been amended to recite that the opening in the vessel wall is defined by a periphery in a thickness of the wall. An occluding member is inserted into the opening and occludes the opening. Claim 66 has been amended to clarify that the occluding member directly contacts the periphery. Support for this language is found, for example, in FIGS. 15C, 15D, 16E, 17B, and 18D. It is respectfully submitted that Nobles does not teach at least these features.

In particular, Nobles discloses a device and method for assisting in end-to-side anastomosis, and includes creating a seal around the inner wall of an incision in a blood vessel.

*Nobles at Abstract.* With the methodology of Nobles, an incision 82 is made in a blood vessel wall 81. A tubular member 12 is inserted through the incision 82, and inverting members 14, 15 are deployed within the vessel 81. The inverting members 14, 15 are then proximally directed to seal the edges of a cup formed by the inverting members 14, 15 against an interior of the vessel wall 81 as shown in FIG. 16. *Nobles at col. 5, l. 57 – col. 6, l. 10.* That is to say, the cup, including the cup edges, is spaced from and does not directly contact a periphery of the incision 82. FIGS. 25D, 26A, and 31 reflect similar methodologies in which an occluding member bears against an interior of the vessel wall 81, but does not directly contact a periphery of the incision/hole 82 formed in the vessel wall as claimed. Thus, claim 66 is allowable over Nobles.

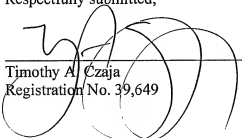
Claims 67, 71, 74, 75, 126, 132-134, 137, and 139-141 depend from claim 66. Notably, the secondary references of Ho, Marks, and LeMole do not address the deficiencies of Nobles with respect to independent claim 66. Thus, claim 67, 71, 74, 75, 126, 132-134, 137, and 139-141 are allowable over the cited art.

### CONCLUSION

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 500471. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call Katrina Witschen at telephone (+1-763) 505-8418.

Respectfully submitted,

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Dated

  
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